

K063167

510(k) SUMMARY

1. 510(k) Owner Name and Address:
PHASEIN AB
Svärdvägen 15
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Sweden
Telephone: 46-8-544-98-150
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2. Contact Person:
David Weissburg
Weissburg Associates
Madison, Wisconsin
Telephone: 1-608-770-0223
3. Date: 28 December 2006 FEB 6 2007
4. Trade Name: EMMA Emergency Capnometer
5. Common Name: Carbon Dioxide Gas Analyzer
6. Classification Names:
 - a. Carbon dioxide gas analyzer (21 CFR 868.1400, Product Code CCK)
7. Substantially equivalent to:
 - a. Tidal Wave Model 610, Novamatrix Medical Systems Inc. (K963327)
 - b. VEO Multigas Monitor for Pocket PC, Phasein AB. (K051857)
8. Device description: The EMMA Emergency Capnometer is a miniature mainstream infrared gas analysis bench with an integrated user interface. The complete carbon dioxide analyzer is contained within a transducer that is attached to the breathing circuit via the EMMA Airway Adapter.
9. Intended Use:

The EMMA Emergency Capnometer Monitor measures, displays and monitors carbon dioxide concentration and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult and pediatric patients.

The EMMA Emergency Capnometer Analyzer measures and displays carbon dioxide concentration and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult and pediatric patients.
10. Comparison to predicates: The EMMA Emergency Capnometer combines carbon dioxide measurement capabilities and enhanced portability. The EMMA Emergency Capnometer uses the same basic technology concepts of the predicate devices, while adding improvements derived from advanced electronics and miniaturization. The intended use of the EMMA Emergency Capnometer and its predicates are equivalent. All the devices utilize disposable single-patient-use airway adapters to interface with gases in the breathing circuit. Labeling and materials used are equivalent.
11. Testing vs. predicates: Testing in direct comparison to predicates throughout the operating range was conducted using calibrated gas samples and legally marketed anesthesia and ventilation devices.
12. Conclusions from testing: The EMMA Emergency Capnometer demonstrated performance, safety and effectiveness equivalent or superior to its predicates in all characteristics.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Phasein AB
C/O Mr. David Weissburg
Weissburg Associates
4213 Winnequah Drive
Madison, Wisconsin 53716

FEB 6 2007

Re: K063167

Trade/Device Name: EMMA Emergency Capnometer
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: January 3, 2007
Received: January 10, 2007

Dear Mr. Weissburg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number: _____

Device Name: EMMA Emergency Capnometer

Indications for Use:

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The EMMA Emergency Capnometer Analyzer measures and displays carbon dioxide concentration and respiratory rate during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, clinic, emergency medicine and emergency transport settings for adult and pediatric patients.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



For the Director, Center for Devices and Radiological Control
U.S. Food and Drug Administration

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